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PATENT
Attorney Docket No. **STRATA-06948**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Allen Comer *et al.*		
Serial No.:	10/087,388	Group No.:	1634
Filed:	03/01/02	Examiner:	Switzer
Entitled:	**Skin Substitutes For Irritancy Testing**		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: October 15, 2003 By: Mary Ellen Waite
Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

Applicant's believe no fee is required. If the Commissioner deems otherwise, the Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: October 15, 2003

J. Mitchell Jones
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By: Mary Ellen Waite
Mary Ellen Waite

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Berger *et al.,* Secreted placental alkaline phosphatase: a powerful new quantitative indicator of gene expression in eukaryotic cells, Gene 66:1-10 (1998)

- Jaspers *et al.,* Arsenite Exposure of Cultured Airway Epithelial Cells Activates κB-dependent Interleukin-8 Gene Expression in the Absence of Nuclear Factor κB Nuclear Translocation, J. Biol. Chem. 274:31025-31033 (1999)
- Muller *et al.,* Enhanced expression of IL-8 in normal human keratinocytes and human keratinocyte cell line HaCaT *in vitro* after stimulation with contact sensitizers, tolerogens and irritants, Exp. Dermatol. 3:298-303 (1994)
- Newby *et al.,* Cytokine Release and Cytotoxicity in Human Keratinocytes and Fibroblasts Induced by Phenols and Sodium Dodecyl Sulfate, Soc. of Investigative Dermatology, 115:292-298 (2000)
- Fisher *et al.,* All-*Trans* Retinoic Acid Induces Cellular Retinol-Binding Protein in Human Skin *In Vivo*, Soc. of Investigative Dermatology, 105:80-86 (1995)
- Wilmer *et al.,* Cytokine Induction in Human Epidermal Keratinocytes Exposed to Contact Irritants and Its Relation to Chemical-Induced Inflammation in Mouse Skin, Soc. of Investigative Dermatology, 102:915-922 (1994)
- Roguet, Cell Biology and Toxicology, 15:64-75 (1999)
- van Ruissen *et al.,* Differential Effects of Detergents on Keratinocyte Gene Expression, Soc. of Investigative Dermatology, 110:358-363 (1998)
- Terunuma *et al.,* Cytokine mRNA profiles in cultured human skin component cells exposed to various chemicals: a simulation model of epicutaneous stimuli induced by skin barrier perturbation in comparison with that due to exposure to haptens or irritant, J. of Dermatological Science, 26:85-93 (2001)
- Medina *et al.,* Use of Human Skin Equivalent Apligraf for *in Vitro* Assessment of Cumulative Skin Irritation Potential of Topical Products, Toxicology and Applied Pharmacology, 164:38-45 (200)
- Muller-Decker *et al.,* Keratinocyte-Derived Proinflammatory key Mediators and Cell Viability as *in Vitro* Parameters of Irritancy: A Possible Alternative to the Draize Skin Irritation Test, Toxicology and Applied Pharmacology, 127:99-109 (1994)
- Abe *et al.,* Interleukin-8 Gene Repression by Clarithromycin Is Mediated By The activator Protein-1 Binding Site in Human Bronchial Epithelial Cells, Am. J. Respir. Cell Mol. Biol., 22:51-60 (2000)

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: October 15, 2003

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FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: STRATA-06948	Serial No.: 10/087,388
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Multiple Sheets If Necessary)		Applicant: Allen Comer *et al.*	
(37 CFR § 1.98(b))		Filing Date: 03/01/02	Group Art Unit:

		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	1	Berger *et al.*, Secreted placental alkaline phosphatase: a powerful new quantitative indicator of gene expression in eukaryotic cells, Gene 66:1-10 (1998)
	2	Jaspers *et al.*, Arsenite Exposure of Cultured Airway Epithelial Cells Activates κB-dependent Interleukin-8 Gene Expression in the Absence of Nuclear Factor κB Nuclear Translocation, J. Biol. Chem. 274:31025-31033 (1999)
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Examiner:	Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.